



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/577,414

04/26/2006

Nigel Cronin

103210-0012

5135

24267 7590 11/13/2009
CESARI AND MCKENNA, LLP
88 BLACK FALCON AVENUE
BOSTON, MA 02210

EXAMINER

HUPCZEY, JR, RONALD JAMES

ART UNIT

PAPER NUMBER

3739

MAIL DATE

DELIVERY MODE

11/13/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/577,414	Applicant(s) CRONIN ET AL.	
	Examiner RONALD HUPCZEY, JR	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 July 2009 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendments and remarks, filed on July 8th, 2009, have been fully considered by the Examiner. Claims 1-15 and 17 are currently pending with claims 1-2, 5-6 and 13-15 amended and claim 17 newly added. Applicant's amendments to the drawings have overcome the previously filed objections and Applicant's amendment to claim 13 has obviated the previously filed rejection under 35 U.S.C. 112 2nd paragraph. Applicant's amendment to claims 1-15 and cancellation of claim 16 have overcome the previously filed rejection under 35 U.S.C. 102(b) in view of Prakash et al (US 2003/0088242 A1). The following is a complete response to the July 8th, 2009 communication.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-15 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1 and 17, claim 1 sets forth that the distal end portion of the metal ferrule is "attached to said proximal end of the dielectric tip member" and further states that the distal end portion "extends into and is surrounded by said proximal end of the dielectric member". Claim 17 recites similarly worded limitations in reference to the "metal member". As currently written, each of the claims is unclear and confusing rendering the scope of the claims unascertainable. Specifically, it is unclear how if the distal end portion of the ferrule extends into and is surround by the proximal end of the dielectric tip member how it is then attached to the

Art Unit: 3739

proximal end of the dielectric tip member. The extension and surrounding by the ferrule would appear to render the attachment at some point past the proximal end. Appropriate correction is required. Claims 2-15 are rejected due to their dependency on above rejected claim 1.

4. Claim 15 recites the limitation "the metal tube" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-4 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Carl et al (US Pat. No. 6,047,216).

Regarding claims 1 and 17, Carl discloses a radiation applicator comprising an axial central conductor (conductor **314**) defining an axis and having a distal end and a proximal end wherein the proximal end is capable of being coupled to a source of electromagnetic radiation, an outer conductor (conductor **312**) having a distal end and a proximal end wherein the outer conductor surrounds the central conductor while being insulated from the central conductor (see figure 3, proximal portion of dielectric core **316** placed between **312** and **314**), an elongate dielectric tip member (distal portion of dielectric core **316**) having a proximal end and surrounding an axial part of the central conductor at the distal end of the central conductor (see figure 3) and a metal ferrule (metal choke **318**) having a distal end portion attached to the

Art Unit: 3739

dielectric member (see figure 3), surrounding a portion of the central conductor and extending parallel along a length of the central conductor wherein the ferrule further has a proximal end attached to the distal end of the outer conductor (see relationship between **318** and **312**, the Examiner notes that the "attached to" limitation is being satisfied by the coupling shown in figure 3 and has been interpreted by the Examiner as not requiring a direct, electrically conductive connection between the two pieces) such that the distal end portion of the ferrule extends into and is surrounded by the proximal end of the dielectric tip member (see relationship of parts in figure 3).

Regarding claim 2, Carl discloses that the distal end portion of the ferrule (choke **318**) and the dielectric tip member to have respective elongate cooperative surfaces (see figure 3, interface between metal choke **318** and distal portion of dielectric core **316**) wherein the ferrule and the dielectric member are fixedly attached to one another via the abutment of those cooperating surfaces such that the joining results in a rigid structure.

Regarding claim 3, Carl discloses for the cooperating surfaces of above claim 2 to include respective radially extending cooperating surfaces (see radial extension of **318** and **316** outwards from the longitudinal axis of the device).

Regarding claim 4, Carl discloses for the cooperating surfaces of claim 2 to have respective annular cooperating surfaces (annular portions of **318** and **316**).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

Art Unit: 3739

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Carl et al (US Pat. No. 6,047,216).

Regarding claim 15, Carl discloses a plurality of measurements of portions of the device to be less than 2.5mm (see at least col. 19; 36 – col. 20; 15) but fails to specifically disclose the diameter of the whole device to be less than 2.5 mm. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made that in view of the disclosed diameters of the parts and antenna in the above section to make the completed device with a

Art Unit: 3739

diameter of less than 2.5mm to maintain the device as minimally invasive and reduce the size of the hole needed for insertion of the device.

11. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Carl et al (US Pat. No. 6,047,216) as applied to claim 2 above, and further in view of Turovskiy et al (US Pat. No. 7,311,703 B2).

Regarding claims 6, Carl discloses the central conductor to contain the inner conductor (conductor **314**) of a cable but fails to specifically recite a metal tube surrounding the central conductor, the ferrule to be attached to the dielectric member and the metal tube and for the metal tube and cable to define an annular space therebetween which permits the passage of cooling fluid. Turovskiy discloses a similar microwave antenna assembly which supplies cooling to the radiating portion of the antenna. Turovskiy further discloses a metal tube (outer tube **508**, see figures 22a-b and col. 17; 41-60) surrounding a portion of the central and outer conductors (conductors **502**, **504**) wherein the tube is spaced apart from the distal end of the central conductor which is surrounded by the dielectric tip member (see any of figures 4D-5E) and wherein the cable and metal tube define an annular space (see fluid channels defined in figures 22A-B between cable and tube) which permits passage of cooling fluid to the distal portion of the antenna. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a metal tube such as that of Turovskiy in combination with the disclosed structure of the antenna of Carl to provide for an applicator which is also cooled. In construction, to provide for a rigid structure capable of being maneuvered to a target portion of tissue, it would advantageous to rigidly secure the metal tube of Turovskiy to the dielectric member via the ferrule of Carl by any common method such as soldering or gluing via epoxy.

Art Unit: 3739

Furthermore, the provision of cooling of a microwave antenna is well known in the art and ensures that the target tissue which is to be treated is not unnecessarily ablated or charred due to heating of the applicator structure and that tissue adjacent the target tissue is protected from being treated due to the cooling provided.

12. Claim 14 rejected under 35 U.S.C. 103(a) as being unpatentable over Carl et al (US Pat. No. 7,311,703 B2) as applied to claim 2 above, and further in view of Prakash et al (US Pub. No. 2003/0088242 A1).

Regarding claim 14, Carl fails to disclose the dielectric member to be formed into a blade wherein the blade has a dimension of elongation transverse to the axis. Prakash discloses a similar radiation applicator in which the tip of the device is tapered to a form a sharpened tip (see figure 5, paragraph [0065]). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a blade such as that of Prakash et al with the applicator of Carl et al to allow for an applicator which is easily advanced into a target portion of tissue. Furthermore, the provision of a sharpened tip (blade) on an applicator is a well known and commonly utilized structure to facilitate the insertion of an applicator into tissue.

13. Claims 7-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carl et al (US Pat. No. 6,047,216) and Turovskiy et al (US Pat. No. 7,311,703 B2) as applied to claim 6 above, and further in view of Ni et al (US Pat. No. 6,514,251 B1).

Regarding claims 7, 8, 10 and 11, Carl and Turovskiy fail to disclose holes provided in the metal tube to provide for fluid conduits between the annular space and the exterior of the application. Ni discloses an applicator which utilizes a cooling system which provides for radially extending holes (see figures 3, 4 and 6, openings **35, 41**) placed in the outer tube of the

Art Unit: 3739

applicator to provide fluid outflow from the annular space to the outside of the applicator. Ni further discloses the holes to be diametrically opposed and for the holes to be spaced apart axially (see placement of holes in figures 3, 4 and 6). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide at least one set of holes in the metal tube of the combined device of Carl et al and Turovskiy et al as displayed by Ni et al to provide for an electrode which cools both the applicator assembly itself and the tissue which is contacted by the applicator in order to prevent unwanted charring and overheating of the target tissue.

Regarding claim 9, Carl, Turovskiy and Ni each fail to specifically recite the number of holes found per set. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide 1 to 4 holes per set in order to provide sufficient fluid outflow to the target tissue. While applicant's specification does recite the criticality of ensuring effective fluid flow, it should be noted that Ni also provides for such a criticality (see col. 4; 1-27) and that the fluid flow rate into the applicator as well as the number of holes would be an obvious variation to the applicator which would directly effect the fluid flow to the exterior of the applicator.

Regarding claim 12, Carl, Turovskiy and Ni each fail to specifically recite the diameter of holes. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a diameter of 0.1 to 0.6mm per hole in order to provide sufficient fluid outflow to the target tissue and to maintain the structural integrity of the applicator. While applicant's specification does recite the criticality of ensuring effective fluid flow, it should be noted that Ni also provides for such a criticality (see col. 4; 1-27) and that the fluid flow rate into

Art Unit: 3739

the applicator as well as the number of holes and the diameter of each hole would be an obvious variation to the applicator which would directly effect the fluid flow to the exterior of the applicator.

Regarding claim 13, Carl, Turovskiy and Ni each fail to specifically recite the location of the holes on the applicator. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a location of anywhere from 3 to 50mm of placement in order to provide for adequate cooling to the portion of target tissue the applicator is inserted into. While applicant's specification does recite the criticality of ensuring effective fluid flow to the portion of tissue to be treated, it should be noted that Ni also provides for such a criticality (see col. 4; 1-27) and that the fluid flow rate into the applicator as well as the location of the holes would be modified as such to ensure that effective cooling is applied to the complete portion of target tissue treated.

Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Art Unit: 3739

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 1-15 and 17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 7-10 and 12-14 of copending Application No. 11/646141. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application recite similar structure and structural relationships between the parts that encompasses the same subject matter as being sought in instant application. While not set forth in the same manner or using the same terms, one of ordinary skill in the art would appreciate that the copending claims encompass overlapping subject matter with the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

16. Claims 1-15 and 17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 7-10 and 12-14 of copending Application No. 12/158,831. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application recite similar structure and structural relationships between the parts that encompasses the same subject matter as being sought in instant application. While not set forth in the same manner or using the same terms, one of ordinary skill in the art would appreciate that the copending claims encompass overlapping subject matter with the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

17. Applicant's arguments filed July 8th, 2009 have been fully considered but they are not persuasive.

While Applicant argues on page 9 that the choke **318** of Carl cannot be considered the ferrule of the instant claims, the Examiner respectfully disagrees. It is noted by the Examiner that both claims 1 and 17 fail to set forth that the applicator is functioning as a dipole radiator (such is introduced in claim 5). Since there is no function associated with the ferrule of claims 1 and 17 which would define it over the choke of Carl, the structure of the choke of Carl and the ferrule of the instant claims is only at issue. Therefore, it is the Examiner's position that in response to the amendments to the claims, the new interpretation set forth above renders Carl still a valid anticipatory reference. It is further noted that claim 5 has only been rejected for nonstatutory double patenting with applications 12/158,831 and 11/646141.

Conclusion

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

Art Unit: 3739

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD HUPCZEY, JR whose telephone number is (571)270-5534. The examiner can normally be reached on Monday - Friday, 9 A.M. to 5 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ronald J. Hupczey/
Examiner, Art Unit 3739

/Michael Peffley/
Primary Examiner, Art Unit 3739

RJH